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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,148	11/05/2003	Michael H. Jones	14875-042004	7576
26161	7590	08/03/2005	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/702,148

Applicant(s)

JONES, MICHAEL H.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.


## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/05/03, 8/23/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claim 25 is pending.
  2. Applicant's species election of SEQ ID NO:1 in the reply on 7/11/05 is acknowledged. Since a prior art revealed no prior art on SEQ ID NO:1, the search has extended to include all of the peptide species.
  3. Sequence Compliance: The instant application appears to be in sequence compliance for patent application containing amino acid sequence disclosures.
  4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).
  5. Applicants' IDS filed on 11/05/03 and 8/23/04 have been considered.
  6. Applicant is required to update US priority in the first line of the specification and update status of all pending applications (The amendment filed on 11/5/03 is not current).
  7. The specification is objected to because of the following informalities:  
p. 19-21, Description of Figures of 6A, 6B, 10, and 13-18 is required to recite SEQ ID NO:s.  
Appropriate correction is required.
  8. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (p. 17, lines 29). Applicant is required to delete the embedded hyperlink and/or other form of browser executable code. See MPEP 608.01 and 608.01(p).
  9. 35 U.S.C. § 101 reads as follows:  
  
"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".
  10. Claim 25 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter; a product of nature.
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Claim 25 as written, does not sufficiently distinguish over antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "gene" recited in claim 25 does not clearly define metes and bounds of the invention.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for an antibody binding to the amino acid sequence consisting of SEQ ID NOs:1, 13, 21, 27 or 29, does not reasonably provide enablement for any antibody binding to at least 60% amino acid sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There is insufficient guidance in the specification as filed as to how the skilled artisan would make and use the antibody to polypeptide having at least 60% amino acid sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29 recited in the instant claim. A person of skill in the art would not know which amino acid is essential to retain binding to SEQ ID NOs:1, 13, 21, 27 or 29. There is insufficient guidance to direct a person of skill in the art to select particular antigen binding fragment. Without detailed direction as to which amino acid is essential to maintain binding to SEQ ID NOs:1, 13, 21, 27 or 29, a person of skill in

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the art would not be able to determine which peptides are capable of binding to an antibody or antigen binding fragment without undue experimentation.

Minor structural differences among structurally related compounds can result in substantially different in solubility, adsorption, or biological activities. Therefore, structurally unrelated compounds comprising antibodies or antigen-binding fragment would be expected to have greater differences in their activities. Colman et al. (Research in Immunology, 145(1):33-36, 1994) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding.

Furthermore, Applicant has no working examples demonstrating binding at least 60% sequence identity to the amino acids SEQ ID NOs:1, 13, 21, 27 or 29.

Accordingly, the specification is not enabling for any antibody binding to the polypeptide having at least 60% sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29 because the specification does not adequately disclose how to make polypeptide having at least 60% sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29 that are functional for practice of the claimed invention.

15. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an antibody capable of binding to the amino acid sequence consisting of SEQ ID NOs:1, 13, 21, 27 or 29; however, applicant is not in possession of any antibody capable of binding to any polypeptide having at least 60% sequence identity to SEQ ID NOs:1, 13, 21, 27 or 29. The phrase "having at least 60% sequence identity to SEQ ID NO:1 (for example)" includes  $3.3 \times 10^{56}$  different amino acid combinations. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

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Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

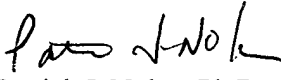
16. No claims are allowable.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim  
Patent Examiner  
Technology Center 1600  
July 28, 2005

  
Patrick J. Nolan, Ph.D.  
Primary Examiner  
Technology Center 1600